

LABORATORY BULLETIN

STATE DOCUMENTS

MONTANA STATE DEPARTMENT OF HEALTH
HELENA, MONTANA

No. 19 - June 25, 1969

THE REGISTRATION OF LABORATORIES AND THE REGISTRATION OF PERSONNEL
PERFORMING TESTS IN THESE LABORATORIES

The Montana State Department of Health is involved with surveillance of clinical laboratory work in three operating areas. First, Regulation 60-001 requires registration of laboratories performing tests for infectious agents; second, the Hospital Licensing Law and regulations containing stipulations concerning laboratory work; third, the Montana State Department of Health, as the "designated agency" for Medicare has responsibility for assuring satisfactory quality in laboratory procedures.

When the above are considered collectively, most laboratory work is included. However, money and personnel-time has never been available in sufficient amount to enable us to satisfactorily meet these responsibilities. The proposed Montana Clinical Laboratory Act of 1969 was an effort to put all of this into a concise legal framework and to obtain financial support. Although the bill failed to pass, we must still assign high priority to these responsibilities because of findings in surveys of the quality of clinical laboratory work in the United States. Results of twenty-five per cent of clinical laboratory tests were found to be in error. Consequently, Congress enacted Public Law 90-174 which contains the Clinical Laboratories Improvement Act of 1967 for laboratories in Interstate Commerce.

The system of registration of laboratories and personnel working in them which has been effect for many years in Montana has been revised and, as we review the files of individual laboratories, you will receive the forms necessary to bring registrations up-to-date. This also involves visiting laboratories, so it will be a slow process as we have no more time or money allotted to this than we ever had. Here is a "breakdown" of the 108 laboratories which are on-file in the Department: Independent Clinical Laboratories - 5; Hospital Laboratories - 69; County Health Department Laboratory - 1; Clinical Laboratories operated by three or more physicians - 31; Blood Banks - 2.

Many are not familiar with the first regulation mentioned above so it is reprinted.

MONTANA STATE BOARD OF HEALTH - REGULATIONS

60-001 REGISTRATION, INSPECTION & APPROVAL OF LABORATORIES - Adopted June 1, 1935
Statutory Authority: RCM 1947 69-4110 (8) 69-4105 Sec. 5 (16)
69-5201 through 5221

Rules and Regulationsa. Examinations by approved laboratories required.

When laboratory examinations are necessary in the investigation of communicable diseases, in ascertaining sources of infection, and in the control or release of a case, contact, or carrier of a communicable disease, the attending physician or health officer shall submit suitable specimens to the State Board of Health Laboratory

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or a laboratory approved by the State Board of Health. The health officer shall by himself or an agent secure and submit final cultures or specimens for examinations.

When laboratory examinations are required by law they shall be done by an approved laboratory.

b. Registration

Every person, firm or corporation operating or maintaining a laboratory in which body fluids, secretions or excretions are examined for the determination of the presence or absence of an infectious agent in the material examined or in the person or animal from which it was secured, shall register annually with the State Board of Health, giving the name of such laboratory, its location, and the name of the person or persons owning or operating the same.

c. Approval

Laboratories which, after inspection, are found to conform to the standards required by the State Board of Health will be given a certificate of approval, and such laboratories will thereafter be designated as approved laboratories.

An authorized representative of the State Laboratory shall make an annual inspection of all registered laboratories, and at such other times as he or the State Board of Health may deem advisable.